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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/686,871	10/16/2003	Mark Czekaj	DEAV1999S005USCIP	7413
5487	7590	12/14/2006		
ROSS J. OEHLER SANOFI-AVENTIS U.S. LLC 1041 ROUTE 202-206 MAIL CODE: D303A BRIDGEWATER, NJ 08807			EXAMINER COLEMAN, BRENDA LIBBY	
			ART UNIT	PAPER NUMBER
			1624	
			MAIL DATE	DELIVERY MODE
			12/14/2006	

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/686,871

Applicant(s)

CZEKAJ ET AL.

Examiner

Brenda L. Coleman

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 25 July 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1,3-8 and 11-29 is/are pending in the application.
- 4a) Of the above claim(s) 26-29 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,3-8 and 11-25 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date <u>6/15/06</u> . | 6) <input type="checkbox"/> Other: _____  |

### **DETAILED ACTION**

Claims 1, 3-8 and 11-29 are pending in the application.

This action is in response to applicant's amendment filed July 25, 2006. Claims 1, 3, 4, 14 and 22-24 have been amended and claims 2, 9 and 10 have been canceled.

#### ***Change of Examiner***

**Note the change of Examiner in the present application.**

#### ***Response to Amendment***

Applicant's arguments filed July 25, 2006 have been fully considered with the following effect:

1. The applicant's amendments and arguments are sufficient to overcome the objection labeled paragraph 6 of the last office action, which is hereby **withdrawn**.
2. The applicant's amendments and arguments are sufficient to overcome the 35 USC § 112, first paragraph rejection labeled paragraph 7 of the last office action, which is hereby **withdrawn**.
3. The applicant's amendments and arguments are sufficient to overcome the 35 USC § 102, anticipation rejection labeled paragraph 8 of the last office action, which is hereby **withdrawn**.
4. The applicant's amendments and arguments are sufficient to overcome the 35 USC § 102, anticipation rejection labeled paragraph 9 of the last office action, which is hereby **withdrawn**.

5. The applicant's amendments and arguments are sufficient to overcome the 35 USC § 102, anticipation rejection labeled paragraph 10 of the last office action, which is hereby **withdrawn**.

6. The applicant's amendments and arguments are sufficient to overcome the 35 USC § 102, anticipation rejection labeled paragraph 11 of the last office action, which is hereby **withdrawn**.

In view of the amendment dated July 25, 2006, the following new grounds of rejection apply:

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

7. Claims 1, 3-8 and 11-25 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The following reasons apply:

a) Claims 1, 3-8, 11-23 and 25 are vague and indefinite in that it is not known what is meant by the variable  $Z^2$  within the definition of  $R^4$  where  $Z^2$  is not defined within the claim.

b) Claims 1, 3-8, 11-23 and 25 are vague and indefinite in that it is not known what is meant by the  $C(=O)-CH_2OH$  and  $C(=O)-CH_2SH$  moieties in the list of acid bioisosteres in claim 1.

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- c) Claims 3, 4 and 23 are vague and indefinite in that it is not known what is meant by the claim dependency where these claims are dependent on a canceled claim.
- d) Claim 14 is vague and indefinite in that it is not known what is meant by the definition of  $R^2$  where  $R^2$  is optionally substituted phenyl or optionally substituted heteroaryl is optionally....
- e) Claim 17 recites the limitation "hydrogen" in the definition of  $R^5$  and  $R^6$ . There is insufficient antecedent basis for this limitation in the claim.
- f) Claim 20 recites the limitation "azaheterocyclyl, azaheterocyclenyl or heteroaryl" in the definition of  $Z^1$ . There is insufficient antecedent basis for this limitation in the claim.
- g) Claim 20 recites the limitation "which **may be** substituted by an amidino substituent" in the definition of  $Z^1$ . There is insufficient antecedent basis for this limitation in the claim.
- h) Claim 20 recites the limitation "at least" in the definition of  $Z^1$ . There is insufficient antecedent basis for this limitation in the claim.
- i) Claim 21 recites the limitation "at least" in the definition of  $Z^1$ . There is insufficient antecedent basis for this limitation in the claim.
- j) Claim 22 recites the limitation "optionally substituted azaheteroaryl, optionally substituted azaheterocyclyl, optionally substituted azaheterocyclenyl, optionally substituted fused arylazaheteroaryl, optionally substituted fused azaheteroarylaryl, optionally substituted fused azaheteroarylcycloalkyl, optionally

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substituted fused azaheteroarylcyloalkenyl, optionally substituted fused azaheteroarylheterocyclyl, optionally substituted fused azaheteroarylheterocyclenyl, optionally substituted fused azaheteroarylazaheterocyclyl, optionally substituted fused azaheteroarylazaheterocyclenyl" in the definition of  $Z^1$ . There is insufficient antecedent basis for this limitation in the claim.

k) Claim 23 is vague and indefinite in that it is not known what is meant by the second occurrence of optionally substituted fused arylcyloalkyl in the definition of  $R^2$ .

l) Claim 23 recites the limitation "optionally substituted fused arylcyloalkyl, optionally substituted fused arylcyloalkyl, optionally substituted fused arylcyloalkenyl, optionally substituted fused arylheteroaryl, optionally substituted fused heteroarylaryl, optionally substituted fused heteroarylcyloalkyl, optionally substituted fused heteroarylcyloalkenyl, optionally substituted fused heteroarylheterocyclyl, optionally substituted fused heteroarylheterocyclenyl" in the definition of  $R^2$ . There is insufficient antecedent basis for this limitation in the claim.

m) Claim 24 is vague and indefinite in that it is not known what is meant by the second occurrence of the species 2-[1-Biphenyl-4-carbonyl)-pyrrolidin-2-yl]-3-(3-carbamimidoylphenyl)-propionic acid methyl ester trifluoroacetate, i.e. the first and seventh species.

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- n) Claim 24 is vague and indefinite in that it is not known what is meant by the nomenclature of the species 2-[1-Biphenyl-4-carbonyl)-pyrrolidin-2-yl]-3-(3-carbamimidoylphenyl)-propionic acid methyl ester trifluoroacetate and 2-[1-Biphenyl-4-carbonyl)-pyrrolidin-2-yl]-3-(4-carbamimidoylphenyl)-propionic acid methyl ester trifluoroacetate, i.e. the seventh and eighth species.
- o) Claim 24 recites the limitation "1H-pyrrolo[3,2-c]pyridine-2-yl" in the nomenclature of the ninth species. There is insufficient antecedent basis for this limitation in the claim.
- p) Claim 24 recites the limitation "1H-pyrrolo[2,3-c]pyridine-2-yl" in the nomenclature of the tenth species. There is insufficient antecedent basis for this limitation in the claim.
- q) Claim 24 recites the limitation "4-amino-quinazolin-6-yl" in the nomenclature of the eleventh species. There is insufficient antecedent basis for this limitation in the claim.
- r) Claim 24 is vague and indefinite in that it is not known what is meant by 6-oxo-16-dihydropyrid-3-yl in nomenclature of the twelfth species.
- s) Claim 24 is vague and indefinite in that it is not known what is meant by the "or" which appears before the fifteenth species indicating the end of the Markush Group which is not so.

***Election/Restrictions***

8. Claims 26-29 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or

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linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on October 28, 2005.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brenda L. Coleman whose telephone number is 571-272-0665. The examiner can normally be reached on 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James O. Wilson can be reached on 571-272-0661. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Brenda L. Coleman  
Primary Examiner Art Unit 1624  
December 1, 2006